# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Mitchell et al.

Serial No.

09/838,858

Examiner

Epps Ford, Janet L.

Filed

April 20, 2001

Group Art Unit:

1635

For

METHOD AND COMPOSITIONS FOR USE IN SPLICEOSOME

MEDIATED RNA TRANS-SPLICING

### INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

August 23, 2004

Carmella L. Stephens

Attorney Name

PTO Registration No

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

Signature

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

- 1. United States Patent Application Serial No. 10/693,192, filed October 23, 2003, "Screening method for identification of efficient pre-trans-splicing molecules," Mitchell et al.
- 2. United States Patent Application Serial No. 10/434,727, filed May 8, 2003, "Use of spliceosome-mediated RNA trans-splicing to confer cell selective replication to adenoviruses," Otto, E.
- 3. United States Patent Application Serial No. 10/374,784, filed February 25, 2003, "Trans-splicing mediated imaging of gene expression," Mitchell et al.
- 4. United States Patent Application Serial No. 10/198,447, filed July 17, 2002, "Spliceosome mediated RNA trans-splicing for correction of skin disorders," Mitchell et al.
- 5. United States Patent Application Serial No. 10/136,723, filed April 30, 2002, "Transgenic animal model for spliceosome-mediated RNA trans-splicing," Puttaraju et al.
- 6. United States Patent Application Serial No. 10/103,294, filed March 30, 2002, "Spliceosome mediated RNA trans-splicing," Mitchell et al.
- 7. United States Patent Application Serial No. 10/075,028, filed March 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 8. United States Patent Application Serial No. 10/076,248, filed February 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 9. United States Patent Application Serial No. 10/941,492, filed August 29, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 10. United States Patent Application Serial No. 09/756,097, filed Jan. 8, 2001,"Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.

- United States Patent Application Serial No. 09/756,095, filed Jan. 8, 2001, published August 22, 2002, as U.S. Patent Publication No. US20020115207, "Method and compositions for use on spliceosome mediated RNA trans-splicing," Mitchell et al.
- 12. United States Patent No. 6,280,978, filed Sept. 23, 1998, issued August 28, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 13. United States Patent Application Serial No. 09/756,096, filed Jan. 8, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 14. United States Patent No. 6,083,702, filed Aug. 13, 1998, issued July 4, 2000, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 15. Mansfield et al., 2000, "Repair of CFTR mRNA by splicesome-mediated RNA trans-splicing," Gene Therapy 7:1885-1895.
- 16. Lan N et al., 1998, "Ribozyme-mediated Repair of Sickle β-Globin mRNAs in Erythrocyte Precursors" Science 280:1593-1596.
- 17. Phylactou LA et al., 1998, "Ribozyme-mediated trans-splicing of a trinucleotide repeat" Nature Genetics 18:378-381.
- 18. Staley JP *et al.*, 1998, "Mechanical Devices of the Spliceosome: Motors, Clocks, Springs and Things" *Cell* 92:315-326.
- 19. Bellet et al., 1997, "Malignant transformation of nontrophoblastic cells is associated with the expression of chorionic gonadotropin  $\beta$  genes normally transcribed introphoblastic cells," Cancer Res. 57:516.
- 20. Coolidge et al., 1997, "Functional analysis of the polypyrimidine tract in premRNA splicing," Nucleic Acids Res. 25:888.

- 21. Malek O et al., 1997, "Evolution of trans-splicing plant mitochondrial introns in pre-Permian times" *Proc. Nat'l. Acad. Sci. USA* 94:553-558.
- 22. Hoon et al., 1996, "Detection of metastatic breast cancer by β-hCG polymerase chain reaction," Int J. Cancer 69:369.
- 23. Jones JT *et al.*, 1996, "Tagging ribozyme reaction sites to follow trans-splicing in mammalian cells" *Nature Medicine* 2:643-648.
- 24. Krämer A, 1996, "The structure and function of proteins involved in mammalian Pre-mRNA splicing" *Annu. Rev. Biochem.* 65:367-404.
- 25. Nisson, 1996, "Multiple affinity domains for the detection, purification, and immobilization of recombinant proteins," J. et al. J. Mol. Recognit., 1996, 5:585-594.
- 26. Pasman Z et al., 1996, "The 5' and 3' splice sites come together via a three dimensional diffusion mechanism" *Nucleic Acids Res.* 24(9):1638-1645.
- 27. Bruzik JP *et al.*, 1995, "Enhancer-dependent interaction between 5' and 3' splice sites in trans" *Proc. Nat'l. Acad. Sci. USA* 92:7056-7059.
- 28. Chiara MD *et al.*, 1995, "A two-step mechanism for 5' and 3' splice-site pairing" *Nature* 375:510-513.
- 29. Davis RE et al., 1995, "RNA Trans-splicing in Flatworms" J. Biol. Chem. 270:21813-21819.
- 30. Eul J et al., 1995, "Experimental evidence for RNA trans-splicing in mammalian cells: EMBO. J. 14(13):3226-3235.
- 31. Hollenberg et al., 1994, "Multiple promoter elements in the human chorionic gonadotropin b subunit genes distinguish their expression from luteinizing hormone β gene," Mol. Cell Endo., 106:111-119.

- 32. Sullenger BA *et al.*, 1994, "Ribozyme-mediated repair of defective mRNA by targeted trans-splicing" *Nature* 341:619-622.
  - 33. Goldspiel et al., 1993, "Human gene therapy," Clinical Pharmacy 12:488-505.
- 34. Kozarsky and Wilson, 1993, "Gene therapy:adenovirus vectors," Current Opinion in Genetics and Development 3:499-503.
- 35. Miller *et al.*, 1993, "Use of adenoviral vectors for gene transfer and expression," Meth. Enzymol. 217:581-599.
- 36. Moore and Sharp, 1993, "Evidence for two active sites in the splicesome provided by sterochemistry of pre-mRNA splicing," Nature, 365:364-368.
- 37. Moore, 1993, "Splicing of precursors to mRNA by the spliceosome," in RNA World, R.F. Gesteland and J.F. Atkins, eds. Cold Spring Harbor Laboratory Press, p303-358.
- 38. Morgan and Anderson, 1993, "Human Gene Therapy," Ann. Rev. Biochem. 62:191-217.
  - 39. Mulligan, 1993, "The basic science of gene therapy," Science 260:926-932.
- 40. Roscigno et al., 1993, "A mutational analysis of the polypyrimidine tract of introns," J. Bio. Chem., 268:11222-11229.
- 41. Tolstoshev, 1993, "Gene therapy, concepts, current trials, and future directions," Ann. Rev. Pharmacol. Toxicol. 33:573-596.
- 42. Acevedo et al., 1992, "Human chorionic gonadotropin-beta subunit gene expression in cultured human fetal and cancer cells of different types and origins," Cancer 76:1467.
- 43. Bruzik JP *et al.*, 1992, "Spliced leader RNAs from lower eukaryotes are transspliced in mammalian cells: *Nature* 360:692-695.

- 44. Vellard M et al., 1992, "A potential splicing factor is encoded by the opposite strand of the trans-spliced c-myb exon" Proc. Nat'l. Acad. Sci., 89:2511-2515.
- 45. Janknecht et al., 1991, "Rapid and efficient purification of native histidine-tagged protein expressed by recombinant vaccinia virus," Proc. Natl. Acad. Sci., 88:8972-8976.
  - 46. Wu and Wu, 1991, "Delivery systems for gene therapy," Biotherapy 3:87-95
  - 47. United States Patent No. 4,980,286, issued Dec. 25, 1990 of Morgan et al.
- 48. Rajkovic A *et al.*, 1990, "A spliced leader is present on a subset of mRNAs from the human parasite *Schistosoma mansoni*" *Proc. Nat'l. Acad. Sci. USA*, 87:8879-8883.
- 49. Schneider et al., 1990, "Building blocks for oligonucleotide analogs with dimethyl-sulfide-sulfoxide and sulfone groups replacing phosphodiester linkages," Tet. Letters, 31:335.
- 50. Senapathy et al., 1990, "Splice junctions, branch point sites, and exons:sequence statistics, identification, and applications to genome project," Methods of Enzymology, 183:252-278.
- 51. Uhlmann et al., 1990, "Antisense oligonucleotides:a new therapeutic principle," Chem Rev., 90:543-549.
- International Patent Application No. PCT/US89/01589, published on November
   1989 as International Publication No. WO89/10134.
- 53. Kerem et al., 1989, "Identification of the Cystic Fibrosis Gene:Genetic analysis," Science, 245:1073-1080.
- 54. Letsinger et al., 1989, "Cholesterol-conjugated oligonucleotides; synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture, " Proc. Natl. Acad. Sci., 86:6553-6556

- 55. Reed, 1989, "The organization of 3' splice sites sequences in mammalian introns," Genes Dev. 3:2113.
- 56. Riordan et al., 1989, "Identification of the Cystic Fibrosis Gene:Cloning and characterization of complementary DNA," Science, 245:1066-1073.
- 57. Rommens et al., 1989, "Identification of the Cystic Fibrosis Gene: Chromosome walking and jumping," Science, 245:1059-1065.
- 58. Shimizu A *et al.*, 1989, "Immunoglobulin double-isotype expression by transmRNA in a human immunoglobulin transgenic mouse" *Proc. Nat'l. Acad. Sci. USA* 86:8020-8023.
- 59. Smith et al., 1989, "Scanning from an independently specified branch point defines the 3' splice site of mammalian introns," Nature, 342-243-247.
- 60. International Patent Application No. PCT/US88/02009 of Synthetic Genetics, published on Dec. 15, 1988 as International Publication No. WO88/09810.
- 61. van der Krol et al., 1988, "Modulation of eukaryotic gene expression by complementary RNA or DNA sequences," BioTechniques, 6:958-976.
- 62. Reed & Maniatis 1988, "The role of the mammalian branchpoint sequence in the pre-mRNA splicing," Genes Dev. 2:1268.
- 63. Smith et al, 1988, "Single-step purification of polypepetides expressed in Escherichia coli as fusions with glutathione S-transferase," Gene, 67:31
- 64. Zon et al., 1988, "Oligonucleotide analogues as potential chemotherapeutic agents," Pharm. Res., 5:539-549.
- 65. Krause M et al., 1987, "A Trans-spliced Leader Sequence on Actin mRNA in C. elegans" Cell 49:753-761.

- 66. Lemaitre et al., 1987, "Specific antiviral activity of a poly(L-lysine)-conjugated oligodeoxyribonucleotide sequence complementary to vesicular stomatitis virus N protein mRNA initiation site," Proc. Natl. Acad. Sci., 84:648-652.
- 67. Wu and Wu, 1987, "Receptor-mediated in vitro gene transformation by a soluble DNA carrier system," J. Biol. Chem., 262:429-4432.
- 68. Murphy et al., 1986, "Identification of a novel Y branch structure as an intermediate in Trypanosome m RNA processing:evidence for Trans splicing," Cell, 47:517.
- 69. Smith et al., 1986, "Mr 26,000 antigen of Schistosoma japonica recognized by resistant WEH1 129/J mice is a parasite glutathione S-transferase," Proc. Natl. Acad. Sci., 83:8703-8707.
- 70. Sutton RE *et al.*, 1986, "Evidence for Trans Splicing in Trypanosomes" *Cell* 47:527-535.
- 71. Konarska MM *et al.*, 1985, "Trans Splicing of mRNA Precursors In Vitro" *Cell* 46:165-171.
  - 72. Solnick D, 1985, "Trans Splicing of mRNA Precursors" Cell 42:157-164.
- 73. Talmadge et al., 1984, "Only three of the seven chorionic gonadotropin beta subunit genes can be expressed in the placenta," Nucleic Acids Res. 12:8415.
- 74. Accession No. K01722, Corynebacteriophage beta diptheria toxin (DT) gene, 1983.
- 75. Greenfield, 1983, "Nucleotide sequence of the structural gene for the diptheria toxin carried by corynebacteriophage β," Proc. Natl. Acad. Sci., 80:6853-6857.
- 76. Brinster et al., 1982, "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs," Nature, 296:39-42.

- 77. Benoist et al., 1981, ""In vivo sequence requirements of the SV40 early promoter region," Nature, 290:304-310.
- 78. Wagner TE *et al.*, 1981, "Microinjection of a rabbit β-globin gene into zygotes and its subsequent expression in adult mice and their offspring" *Proc. Natl. Acad. Sci. USA* 78(10):6376-6380.
- 79. Yamamoto et al., 1980, "Identification of a functional promoter in the long terminal repeat of Rous Sarcoma Virus," Cell, 22:39-42.
- 80. Berget SM et al., 1977, "Spliced segments at the 5' terminus of adenovirus 2 late mRNA" Proc. Natl. Acad. Sci. USA 74(8):3171-3175.
- 81. Chow LT *et al.*, 1977, "An Amazing Sequence Arrangement at the 5' Ends of Adenovirus 2 Messenger RNA" *Cell* 12:1-8.
- 82. Uchida et al, 1973, "Diptheria toxin and related proteins: isolation and properties of mutant proteins related to diptheria toxin," J. Biol. Chem., 248:3838.

References #1-11 and 13 are related co-pending U.S. patent applications.

Identification of the above-listed citations is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application.

Pursuant to 37 C.F.R. § 1.97(c), this Information Disclosure Statement is being filed, the applicants believe, before the mailing date of a final action, notice of allowance or other action that otherwise closes prosecution and is accompanied by the fee set forth in §1.17(p). However, if any additional fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted, BAKER BOTTS L.L.P.

Rochelle K. Seide

Patent Office Reg. No. 32,300

Carmella L. Stephens

Patent Office Reg. No. 41,328

30 Rockefeller Plaza

44th Floor

New York, NY 10112

(212) 408-2500

Attorneys for Applicants

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office

Atty. Docket No. A31304BAD 069906.0144 Serial No. 09/838,858

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

se several sheets if necessary)

Applicant
Mitchell et al.

Mitchell et al

Filing Date Group
April 20, 2001 1635

AUS 2 5 2004

### **U.S. PATENT DOCUMENTS**

*Exa m. Init.				Doc	umen	t No.			Date	Name	Class	Subclass	Filing Date ifAppropriate
-	12	6	2	8	0	9	7	8	8/28/01	Mitchell et al.	435	91.3	
	14	6	0	8	3	7	0	2	7/4/00	Mitchell et al.	435	6	
	47	4	9	8	0	2	8	6	12/25/90	Morgan et al.	435	1723	

#### FOREIGN PATENT DOCUMENT

•				Doo	cument	t No.			Date		Country	Class	SubClass	Translation Yes No	
	52	8	9	1	0	1	3	4	11/2/89	WIPO					
-	60	8	8	0	9	8	1	0	12/15/88	WIPO	<del></del>				

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

1	United States Patent Application Serial No. 10/693,192, filed Oct. 23, 2003, "Screening method of identification of efficient pre- trans-splicing molecules," Mitchell et al.
2	United States Patent Application Serial No. 10/434,727, filed May 8, 2003, "Use of spliceosome-mediated RNA trans-splicing to confer cell selective replication to adenoviruses," Otto, E.
3	United States Patent Application Serial No. 10/374,784, filed February 25, 2003, "Trans-splicing mediated imaging of gene expression," Mitchell et al.
4	United States Patent Application Serial No. 10/198,447, filed July 17, 2002, "Spliceosome mediated RNA trans-splicing for correction of skin disorders," Mitchell et al.
5	United States Patent Application Serial No. 10/136,723, filed April 30, 2002, "Transgenic animal model fo spliceosome-mediated RNA trans-splicing," Puttaraju et al.

NY02:492949.1

1

Examiner

Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	Patent and Trademark Office	A31304BAD 069906.0144	09/838,858	
INFORM	IATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.		
OLD E 10	(Use several sheets if necessary)	Filing Date April 20, 2001	Group 1635	
AUG 2 5 2004				
THE TRUE	United States Patent Application Serial No RNA trans-splicing," Mitchell et al.	o. 10/103,294, filed March 30, 200	2, "Spliceosome mediated	
7	United States Patent Application Serial No for use in spliceosome mediated RNA trans	o. 10/075,028, filed March 12, 200 as-splicing," Mitchell et al.	2, "Method and compositions	
8	United States Patent Application Serial No compositions for use in spliceosome media			
9	United States Patent Application Serial No for use in spliceosome mediated RNA trans	o. 10/941,492, filed August 29, 200 as-splicing," Mitchell et al.	01, "Method and compositions	
10	United States Patent Application Serial No use on spliceosome mediated RNA trans-s	o. 09/756,097, filed Jan. 8, 2001, " plicing," Mitchell et al.	Method and compositions for	
11	United States Patent Application Serial No. U.S. Patent Publication No. US200201152 RNA trans-splicing," Mitchell et al.	o. 09/756,095, filed Jan. 8, 2001, p 207, "Method and compositions for	ublished August 22, 2002, as ruse on spliceosome mediated	
13	United States Patent Application Serial No use on spliceosome mediated RNA trans-s		Method and compositions for	
15	Mansfield et al., 2000, "Repair of CFTR m Therapy 7:1885-1895.	RNA by splicesome-mediated RN	IA trans-splicing," Gene	
16	Lan N et al., 1998, "Ribozyme-mediated re Science 280:1593-1596.	epair of Sickle β-Globin mRNAs i	n Erythrocyte Precursors"	
17	Phylactou LA <i>et al.</i> , 1998, "Ribozyme-med 18:378-381.	diated trans-splicing of a trinucleo	tide repeat" Nature Genetics	
18	Staley JP et al., 1998, "Mechanical Device 92:315-326.	s of the Spliceosome: Motors, Clo	ocks, Springs and Things" Cel	
NY02:492949.1		2		
Examiner	Date Cons	sidered		

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

		U.S. Department of Commerce tent and Trademark Office	Atty. Docket No. A31304BAD 069906.0144	Serial No. 09/838,858
INFO	RMAT	TION DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.	
OIP 5	Use	e several sheets if necessary)	Filing Date April 20, 2001	Group 1635
AUG 2 5	2004 麗			
STENTA RA	9 AN	Bellet et al., 1997, "Malignant transformate chorionic gonadotropin β genes normally	tion of nontrophoblastic cells is as transcribed introphoblastic cells,"	sociated with the expression of Cancer Res. 57:516.
2	20	Coolidge et al., 1997, "Functional analysis Acids Res. 25:888.	s of the polypyrimidine tract in pre	e-mRNA splicing," Nucleic
2	21	Malek O et al., 1997, "Evolution of trans- Nat'l. Acad. Sci. USA 94:553-558.	splicing plant mitochondrial intror	ns in pre-Permian times" Proc.
2	.22	Hoon et al., 1996, "Detection of metastatic Cancer 69:369.	c breast cancer by β-hCG polymer	ase chain reaction," Int J.
. 2	.3	Jones JT et al., 1996, "Tagging ribozyme in Medicine 2:643-648.	reaction sites to follow trans-splic	ing in mammalian cells" Natur
2	.4	Krämer A, 1996, "The structure and function Annu. Rev. Biochem. 65:367-404.	ion of proteins involved in mamma	alian Pre-mRNA splicing"
2	:5	Nisson, 1996, "Multiple affinity domains of proteins," J. et al. J. Mol. Recognit., 1996,		immobilization of recombinan
2	6	Pasman Z et al., 1996, "The 5' and 3' splice mechanism" Nucleic Acids Res. 24(9):163		dimensional diffusion
2	7	Bruzik JP et al., 1995, "Enhancer-depende Acad. Sci. USA 92:7056-7059.	ent interaction between 5' and 3' s	plice sites in trans" Proc. Nat'l
2	8	Chiara MD et al., 1995, "A two-step mech	anism for 5' and 3' splice-site pair	ring" Nature 375:510-513.
2	9	Davis RE et al., 1995, "RNA Trans-splicir	ng in Flatworms" J. Biol. Chem. 2	70:21813-21819.
3	0	Eul J et al., 1995, "Experimental evidence 14(13):3226-3235.	for RNA trans-splicing in mamma	alian cells: EMBO. J.
NY02:492949	9.1		3	
Examiner		Date Con	sidered	

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form	PTO-144	19 U.S.	Department of Comr	nerce
(REV	. 2-82)	Patent	and Trademark Offic	e

Atty. Docket No. A31304BAD 069906.0144 Serial No. 09/838,858

### INFORMATION DISCLOSURE STATEMENT **BY APPLICANT**

**Applicant** Mitchell et al.

Filing Date

Group 1635

(Use several sheets if necessary)

1. 2. 45	se several sheets if necessary)	April 20, 2001	1635
8 2 5 2004 B			
4 TRATEMENT	Hollenberg et al., 1994, "Multiple pr distinguish their expression from lut	romoter elements in the human einizing hormone β gene," Mol	chorionic gonadotropin b subunit genes . Cell Endo., 106:111-119.
32	Sullenger BA et al., 1994, "Ribozyn	ne-mediated repair of defective	mRNA by targeted trans-splicing"
33	Nature 341:619-622.  Goldspiel et al., 1993, "Human gene	therapy," Clinical Pharmacy 12	2:488-505.
34	Kozarsky and Wilson, 1993, "Gene Development 3:499-503.	herapy:adenovirus vectors," Cu	arrent Opinion in Genetics and
35	Miller et al., 1993, "Use of adenovir 599.	al vectors for gene transfer and	expression," Meth. Enzymol. 217:581-
36	Moore and Sharp, 1993, "Evidence f mRNA splicing," Nature, 365:364-3		some provided by sterochemistry of pre
37	Moore, 1993, "Splicing of precursors J.F. Atkins, eds. Cold Spring Harbor	s to mRNA by the spliceosome, Laboratory Press, p303-358.	" in RNA World, R.F. Gesteland and
38	Morgan and Anderson, 1993, "Huma	nn Gene Therapy," Ann. Rev. B	iochem. 62:191-217.
39	Mulligan, 1993, "The basic science of	of gene therapy," Science 260:9	26-932.
40	Roscigno et al., 1993, "A mutational 268:11222-11229.	analysis of the polypyrimidine	tract of introns," J. Bio. Chem.,
41	Tolstoshev, 1993, "Gene therapy, con Toxicol. 33:573-596.	ncepts, current trials, and future	directions," Ann. Rev. Pharmacol.
42	Acevedo et al., 1992, "Human choric and cancer cells of different types an	onic gonadotropin-beta subunit p d origins," Cancer 76:1467.	gene expression in cultured human feta
 Y02:492949.1		4	
Examiner	Da	te Considered	

Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

			S. Department of Commerce nt and Trademark Office	Atty. Docket No. A31304BAD 069906.0144	Serial No. 09/838,858	
INI	FORM	/ATIO	ON DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.		
OIP	E ,	(Use s	everal sheets if necessary)	Filing Date April 20, 2001	Group 1635	
AUS Z	5 2004	FEEE				
ATEM & T	ANEWS		Bruzik JP et al., 1992, "Spliced leader RNA Nature 360:692-695.	As from lower eukaryotes are tran	s-spliced in mammalian cells:	
	44		Vellard M et al., 1992, "A potential splicin myb exon" Proc. Nat'l. Acad. Sci., 89:2511		e strand of the trans-spliced c-	
,	45		Janknecht et al., 1991, "Rapid and efficient recombinant vaccinia virus," Proc. Natl. Ad	purification of native histidine-tacad. Sci., 88:8972-8976.	gged protein expressed by	
	46		Wu and Wu, 1991, "Delivery systems for g 1990 of Morgan et al.	gene therapy," Biotherapy 3:87-95	. 4,980,286, issued Dec. 25,	
•	48		Rajkovic A <i>et al.</i> , 1990, "A spliced leader i Schistosoma mansoni" Proc. Nat'l. Acad. S		rom the human parasite	
- 4*	49	:	Schneider et al., 1990, "Building blocks for sulfone groups replacing phosphodiester lines."	r oligonucleotide analogs with din nkages," Tet. Letters, 31:335.	nethyl-sulfide-sulfoxide and	
	50	- 3	Senapathy et al., 1990, "Splice junctions, band applications to genome project," Method	ranch point sites, and exons:seque ods of Enzymology, 183:252-278.	nce statistics, identification,	
	51	1	Uhlmann et al., 1990, "Antisense oligonucl	eotides:a new therapeutic principl	e," Chem Rev., 90:543-549.	
	53	]	Kerem et al., 1989, "Identification of the C	ystic Fibrosis Gene:Genetic analy	sis," Science, 245:1073-1080.	
	54	i	Letsinger et al., 1989, "Cholesterol-conjugation inhibitors of replication of human immunoc 6556	ated oligonucleotides;synthesis, pr deficiency virus in cell culture, " F	roperties, and activity as Proc. Natl. Acad. Sci., 86:6553	
	55	1	Reed, 1989, "The organization of 3' splice s	sites sequences in mammalian intr	ons," Genes Dev. 3:2113.	
	56		Riordan et al., 1989, "Identification of the Complementary DNA," Science, 245:1066-	Cystic Fibrosis Gene:Cloning and 1073.	characterization of	
NY02:492	2949.1			5		
Exami	ner		Date Cons	idered		

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304BAD 069906.0144	Serial No. 09/838,858
INFORMATION DISCLOSURE STATEMENT	Applicant	

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

A31304BAD 069906.0144	09/838,858	
Applicant Mitchell et al.		
Filing Date April 20, 2001	Group 1635	

Examiner	Date Considered
 NY02:492949.1	6
69	Smith et al., 1986, "Mr 26,000 antigen of Schistosoma japonica recognized by resistant WEH1 129/J mice is a parasite glutathione S-transferase," Proc. Natl. Acad. Sci., 83:8703-8707.
68	Murphy et al., 1986, "Identification of a novel Y branch structure as an intermediate in Trypanosome m RNA processing:evidence for Trans splicing," Cell, 47:517.
67	Wu and Wu, 1987, "Receptor-mediated in vitro gene transformation by a soluble DNA carrier system," J. Biol. Chem., 262:429-4432.
66	Lemaitre et al., 1987, "Specific antiviral activity of a poly(L-lysine)-conjugated oligodeoxyribonucleotide sequence complementary to vesicular stomatitis virus N protein mRNA initiation site," Proc. Natl. Acad. Sci., 84:648-652.
65	Krause M et al., 1987, "A Trans-spliced Leader Sequence on Actin mRNA in C. elegans" Cell 49:753-761
64	Zon et al., 1988, "Oligonucleotide analogues as potential chemotherapeutic agents," Pharm. Res., 5:539-549.
63	Smith et al, 1988, "Single-step purification of polypepetides expressed in Escherichia coli as fusions with glutathione S-transferase," Gene, 67:31
. 62	Reed & Maniatis 1988, "The role of the mammalian branchpoint sequence in the pre-mRNA splicing," Genes Dev. 2:1268.
61	van der Krol et al., 1988, "Modulation of eukaryotic gene expression by complementary RNA or DNA sequences," BioTechniques, 6:958-976.
59	Smith et al., 1989, "Scannine from an independently specified branch point defines the 3' splice site of mammalian introns," Nature, 342-243-247.
58	Shimizu A et al., 1989, "Immunoglobulin double-isotype expression by trans-mRNA in a human immunoglobulin transgenic mouse" Proc. Nat'l. Acad. Sci. USA 86:8020-8023.
. 57	Rommens et al., 1989, "Identification of the Cystic Fibrosis Gene: Chromosome walking and jumping," Science, 245:1059-1065.

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office			Atty. Docket No. A31304BAD 069906.0144	Serial No. 09/838,858			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			Applicant Mitchell et al.				
			Filing Date April 20, 2001	Group 1635			
AUG 2	5 2004 g						
ATENT : TH	6	Sutton RE et al., 1986, "Evidence for Tran	ns Splicing in Trypanosomes" Cell	7 47:527-535.			
7	1	Konarska MM et al., 1985, "Trans Splicin	g of mRNA Precursors In Vitro" (	Cell 46:165-171.			
7:	2	Solnick D, 1985, "Trans Splicing of mRNA Precursors" Cell 42:157-164.					
7.	3	Talmadge et al., 1984, "Only three of the s in the placenta," Nucleic Acids Res. 12:84		subunit genes can be expresse			
. 74	4	Accession No. K01722, Corynebacterioph	age beta diptheria toxin (DT) gene	e, 1983.			
75	5	Greenfield, 1983, "Nucleotide sequence of corynebacteriophage β," Proc. Natl. Acad.		ria toxin carried by			
76	6	Brinster et al., 1982, "Regulation of metall eggs," Nature, 296:39-42.	othionein-thymidine kinase fusior	plasmids injected into mouse			
77	7	Benoist et al., 1981, ""Invivo sequence rec 310.	quirements of the SV40 early pron	noter region," Nature, 290:304			
78	3	Wagner TE et al., 1981, "Microinjection o expression in adult mice and their offspring	f a rabbit β-globin gene into zygot g" Proc. Natl. Acad. Sci. USA 78(	tes and its subsequent 10):6376-6380.			
79	9	Yamamoto et al., 1980, "Identification of a Sarcoma Virus," Cell, 22:39-42.	functional promoter in the lond to	erminal repeat of Rous			
80	)	Berget SM et al., 1977, "Spliced segments Acad. Sci. USA 74(8):3171-3175.	at the 5' terminus of adenovirus 2	late mRNA" Proc. Natl.			
1	' '						
NY02:492949	.1		7				
Examiner		Date Cons	sidered				

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-14	19 U.S. Department of Commerce
	Patent and Trademark Office

Atty. Docket No.	
A 3 1 3 0 / P A TO 0 6 0 0 0 6	r

Serial No. 09/838,858

## INFORMATION DISCLOSURE STATEMENT **BY APPLICANT**

(Use several sheets if necessary)

**Applicant** 

Mitchell et al.

Filing Date April 20, 2001

Group 1635

W6 25 2	004 E		
ENT & TR	81	Chow LT et al., 1977, "An Amazing Sequence Arrangement at the 5' Ends of Adenovirus 2 Messenger RNA" Cell 12:1-8.	
	82	Uchida et al, 1973, "Diptheria toxin and related proteins: isolation and properties of mutant proteins relate to diptheria toxin," J. Biol. Chem., 248:3838.	d
•			
7	•		
NY02:492949.1 8		8	
Examiner		Date Considered	

Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.